IN THE UNITED STATES DISTRICT COURT FOR THE

DISTRICT OF MASSACHUSETTS

DR. BERISH RUBIN AND DR. SYLVIA L. ANDERSON Plaintiffs, v. THE GENERAL HOSPITAL CORPORATION, Defendant.	Civil Action No.: 1:09-cv-10040-PBS

MEMORANDUM IN SUPPORT OF
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and D. Mass. Local Rule 56.1, Defendant The General Hospital Corporation ("MGH") hereby moves this Court for summary judgment on Counts I and II on the ground that Plaintiffs Dr. Berish Rubin and Dr. Sylvia L. Anderson cannot prove that they should be named as inventors of U.S. Patent Nos. 7,388,093 ("the '093 patent") and 7,407,756 ("the '756 patent") (collectively, the "patents-in-suit") in light of their admissions and the applicable law. There is no genuine dispute as to any material fact relating to Plaintiffs' claims, and MGH is entitled to judgment as a matter of law.

INTRODUCTION

Plaintiffs brought this action to challenge the inventorship of the patents-in-suit, both of which are assigned to MGH. Two MGH employees, Dr. Susan A. Slaugenhaupt and Dr. James F. Gusella (collectively, "the MGH scientists"), are the named inventors of the patents-in-suit. The patents-in-suit claim inventions relating to the MGH scientists' discovery of two genetic mutations (referred to as the "major" and "minor" mutations) that are associated with Familial Dysautonomia ("FD"). FD, also known as the Riley-Day Syndrome, is a rare birth defect primarily affecting the Ashkenazi (Eastern European)

Jewish population. There is no known cure for FD; one-half of those afflicted typically die by age thirty. The inventions claimed by the patents-in-suit enable the prenatal diagnosis of FD in families that may be affected by the disease. This allows the detection of persons who are carriers of the mutations who are at risk for producing a child afflicted with the disease.

The patents-in-suit are related and claim priority to a provisional patent application that the MGH scientists filed on January 6, 2001 (U.S. Serial No. 60/260,080).[1] Claim 1 of the '756 patent reads:

> 1. A method for assaying for the presence of a mutation associated with Familial Dysautonomia in a human subject, said method comprising detecting the presence of a FD1 [major] mutation wherein the thymine nucleotide at position 34,201 of SEQ ID NO: 1 is replaced by a cytosine nucleotide, or a FD2 [minor] mutation wherein the guanine nucleotide at position 33,714 of SEQ ID NO: 1 is replaced by a cytosine nucleotide in DNA or RNA from a biological sample from said human.

Claim 1 of the '093 patent reads:

> 1. A kit for assaying for the presence of a mutation associated with Familial Dysautonomia in an individual comprising primers 18F (SEQ ID NO:82) and 23R (SEQ ID NO:84) that are capable of amplifying a region of IKBKAP of sufficient size to detect a FD1 [major] mutation at position 34,201 of SEQ ID NO:1 or a FD2 [minor] mutation at position 33,714 of SEQ ID NO:1, wherein said region amplified comprises a FD1 [major] mutation at position 34,201 of SEQ ID NO:1 or a FD2 [minor] mutation at position 33,714 of SEQ ID NO:1.

The remaining claims of the patents-in-suit are similar and all include FD1 and/or FD2, i.e., the major and/or minor mutations discovered by the MGH scientists.

Plaintiffs' Complaint consists of two counts brought under 35 U.S.C. § 256. In Count I, Plaintiffs ask the Court to remove Dr. Slaugenhaupt and Dr. Gusella as the inventors named on the patents-in-suit and instead name Plaintiffs as the inventors. Complaint, Jan. 12, 2009 (Doc. No. 1), ¶¶ 26-31. In Count II, Plaintiffs ask the Court to add them as co-inventors to the patents-in-suit. *Id.* at ¶¶ 32-34. This Court dismissed Plaintiffs' sole remaining count, Count III, on November 22, 2010.

On January 17, 2001, eleven days after Dr. Slaugenhaupt and Dr. Gusella filed their provisional

[1] *See* Exhibit 17.

patent application claiming the mutations, Plaintiffs filed a provisional patent application (U.S. Serial No. 60/262,284) directed to those same mutations.[2] In view of their earlier filing, Dr. Slaugenhaupt and Dr. Gusella are presumed to have made their invention (i.e., discovered the mutations) before Plaintiffs. *Yasuko Kawai v. Metlesics*, 480 F.2d 880, 886 (CCPA 1973). The Patent Office provides a method to rebut this presumption: an interference under 35 U.S.C. § 135. Rather than availing themselves of this procedure, by attempting to prove that they discovered the mutations before the MGH scientists did, Plaintiffs are trying to overturn the presumption that the MGH scientists are the correctly named inventors of the patents-in-suit by improperly invoking 35 U.S.C. § 256 to change the inventorship of the issued patents-in-suit.

Section 256 is used to change inventorship when the inventors are misnamed on work coming out of a collaboration. However, Plaintiffs' have admitted that they did not collaborate with the MGH scientists. Plaintiffs' evidence of their alleged prior inventorship consists of the unwitnessed laboratory records of Plaintiff Dr. Anderson and the uncorroborated testimony of Dr. Anderson and co-Plaintiff Dr. Rubin. Plaintiffs have not produced any evidence to corroborate their claims of inventorship, much less their claims that they are the first inventors. Accordingly, and as set forth more fully below, Plaintiffs cannot as a matter of law satisfy the threshold requirements necessary to invoke 35 U.S.C. § 256. Summary judgment in favor of MGH is, therefore, proper.

At this juncture MGH does not have the burden to substantiate that Dr. Slaugenhaupt's and Dr. Gusella's dates of invention are before Plaintiffs' purported dates of invention. To provide additional context, however, and to demonstrate that MGH would have no difficulty establishing dates of invention that are before the dates that Plaintiffs claim as their dates of invention,[3] MGH supplies the following historical background.

[2] *See* Exhibit 16.

[3] Plaintiffs claim to have discovered the major mutation no earlier than August 15, 2000 and the minor mutation no earlier than September 15, 2000. Plaintiffs' Response to MGH's Requests for Admissions Nos. 1-2, Jan. 19, 2010 ("Plaintiffs' Admissions") at 4 (copy attached hereto as Exhibit 1).

BACKGROUND

Dr. Gusella began his research on the genetic cause of FD in the 1980's. Dr. Slaugenhaupt joined him in his efforts in the early 1990's and, by 2000, was managing the research on a day-to-day basis. In the 1990's, that research led to the development of a genetic marker test that permitted the identification of individuals who carried the FD disease with approximately 95% accuracy. Dr. Slaugenhaupt, Dr. Gusella, and others at MGH obtained several patents on these genetic markers. *See, e.g.*, U.S. Patent Nos. 5,387,506; 5,998,133; and 6,262,250.

Dr. Slaugenhaupt's and Dr. Gusella's research culminated in their discovery of the two mutations of the specific gene that cause FD. The gene is called "IKBKAP" (sometimes referred to as the "IKAP" gene because it is responsible for creating the protein also known as "IKAP"), and is located on human chromosome 9. In early May 2000 Dr. Slaugenhaupt and Dr. Gusella discovered the major mutation. The major mutation involves the transition of a single DNA nucleotide at a specific location on the gene between "T" (thymine) and "C" (cytosine) and is responsible for causing FD in the vast majority of afflicted individuals.

In early August 2000 Dr. Slaugenhaupt and Dr. Gusella discovered the minor mutation. The minor mutation involves the transition of a single DNA nucleotide at a second specific location on the gene between "G" (guanine) and "C" (cytosine). The minor mutation causes FD in a small number of afflicted individuals (approximately four individuals worldwide). Either the major mutation or the minor mutation will convert the gene from normal to "mutant" (i.e., abnormal).

The MGH scientists described their discoveries in their scientific paper published in January 2001 (Slaugenhaupt et al., *Tissue-Specific Expression of a Splicing Mutation in the IKBKAP Gene Causes Familial Dysautonomia*, 68 Am. J. Hum. Gent. 598 (2001) (copy attached hereto as Exhibit 2A)). The mutations are the subject of the patents-in-suit.

Corroboration of the MGH Scientists' Dates of Invention

MGH's evidence supporting Dr. Slaugenhaupt's and Dr. Gusella's earlier dates of invention is

overwhelming and includes MGH's laboratory records, the testimony of MGH's current and former laboratory technicians (none of whom are inventors of the patents-in-suit), contemporaneous correspondence between MGH personnel and disinterested third parties, and the testimony of disinterested third parties who contributed to Dr. Slaugenhaupt's and Dr. Gusella's research in the years leading up to their discoveries.

All of this evidence corroborates Dr. Slaugenhaupt's and Dr. Gusella's own testimony of their dates of invention. Dr. Slaugenhaupt testified that following her review of the laboratory records that her technicians generated, she recognized that she and Dr. Gusella had discovered the major mutation by early May 2000 and the minor mutation by early August 2000. Tr. Slaugenhaupt Dep., Jan. 26, 2010 ("Slaugenhaupt Tr. I") at 29:8-23, 32:8-35:19, 63:3-5; Mann Dep. Ex. 75 (cited in Slaugenhaupt Dep.) (*see* Exhibit 3A). Dr. Gusella provided similar testimony as to the dates of invention. Tr. Gusella Dep., Mar. 2, 2010 ("Gusella Tr. II") at 114:14-16, 121:4-12, 146:1-147:10, 214:8-11, 258:13-259:3; Mann Dep. Ex. 75 (cited in Gusella Dep.) (*see* Exhibit 4B). Gusella Dep. Ex. 112 (*see* Exhibit 4A). The technicians, Ms. Sandra Mann (formerly Sandra Gill) and Mr. James Mull, are not inventors of the patents-in-suit. Both testified in detail about their laboratory records. In her deposition, Ms. Mann examined her laboratory records and testified how certain pages documented experiments that she performed in April 2000 led to the identification of the major mutation. Tr. Mann Dep., Nov. 17, 2009 ("Mann Tr.") at 127:16-128:6; Dep. Ex. 65 at MGH-P000009939 (*see* Exhibit 5). Mr. Mull also provided testimony regarding experiments that he performed in the summer of 2000 that confirmed the discovery of the minor mutation, as well as his recollection of the discovery of the major and minor mutations. Tr. Mull Dep., Feb. 3, 2010 ("Mull Tr.") at 65:19-68:9, 74:2-16, 120:4-6, 131:1-11, 170:14-24 (*see* Exhibit 6). In both instances, Ms. Mann and Mr. Mull were performing their experiments under the direction of Dr. Slaugenhaupt and Dr. Gusella. Mann Tr., 14:4-15:10, 25:6-11. Mull Tr., 18:14-19:9, 20:23-21:5.

Further corroboration of Dr. Slaugenhaupt's and Dr. Gusella's discovery of the major mutation is provided by Dr. Slaugenhaupt's purchase of laboratory supplies, specifically, "primers." Primers are

chemicals used in experiments on DNA that are configured to identify precise sequences of nucleotides. On June 5, 2000 Dr. Slaugenhaupt placed an order for a primer that she identified as "mutant" and another primer that she identified as "normal." *See* MGH-P000004993 and MGH-P000004994, respectively (copies attached hereto as Exhibit 7). The "normal" primer includes the sequence "… AGT G-3' " and the "mutant" primer includes the sequence "… AGC G-3'. " *Id.* (emphasis added). Therefore, by June 5, 2000, Dr. Slaugenhaupt clearly knew that the mutant sequence had the "C" nucleotide in a specific location instead of the "T" nucleotide that is present in that same location in the normal sequence. In other words, by the time Dr. Slaugenhaupt placed her order for primers, the MGH scientists had identified a T/C transition at a specific location in the gene and understood that transition to be the "mutant," i.e., the major mutation. The June 5, 2000 date of the order is consistent with and corroborates Dr. Slaugenhaupt's and Dr. Gusella's early May 2000 discovery of the major mutation. Also, it demonstrates that the MGH scientists discovered the major mutation before Plaintiffs in view of Plaintiffs' admission that they themselves do not claim to have discovered the major mutation before August 15, 2000. Plaintiffs' Admissions, 4.

Dr. Claus Scheidereit of the Max Delbrueck Centrum for Molecular Medicine in Berlin, Germany also provided testimony that further corroborates Dr. Slaugenhaupt's and Dr. Gusella's discovery of the major mutation. Dr. Scheidereit assisted the MGH scientists with their research on FD beginning in February 2000 when he provided them with an antibody that could help with their investigation. Tr. Scheidereit Dep., Feb. 9, 2010 ("Scheidereit Tr.") at 84:6-13; Dep. Exs. H3, H4 (*see* Exhibit 8). Later, in his June 8, 2000 email, Dr. Scheidereit discusses "the mutation." Dr. Scheidereit testified that, when using this phrase, he was referring to the major mutation. Scheidereit Tr., 21:9-23:12; Dep. Ex. H2. Dr. Scheidereit also testified that his email was in response to earlier emails from Dr. Slaugenhaupt in which she identified the major mutation, and that he understood that the MGH scientists had in fact identified the major mutation sometime before June 8, 2000. Scheidereit Tr., 19:5-16; 21:9-22:11. Dr. Scheidereit's testimony and documents provide corroboration of Dr. Slaugenhaupt's and Dr. Gusella's

discovery of the major mutation before Plaintiffs' claim of discovery. Given that Dr. Scheidereit is not affiliated with MGH (Scheidereit Tr., 11:2-10) and is not an inventor of the patents-in-suit, his status as a disinterested third party makes his evidence significant and compelling.

Dr. Felicia B. Axelrod of the New York University School of Medicine and Dr. Michael J. Brownstein, formerly of the National Institutes of Health, are additional individuals who have corroborated Dr. Slaugenhaupt's and Dr. Gusella's discovery of the major mutation. Both Dr. Axelrod and Dr. Brownstein have provided declarations[4] describing their contributions to the MGH scientists' research on FD. Decl. of Felicia B. Axelrod, M.D., Jan. 3, 2011 ("Axelrod Decl.") ¶¶ 10-17 (copy attached hereto as Exhibit 9); Decl. of Michael J. Brownstein, M.D., Ph.D., Dec. 30, 2010 ("Brownstein Decl.") ¶¶ 11-15 (copy attached hereto as Exhibit 10). Dr. Axelrod and Dr. Brownstein communicated regularly with Dr. Slaugenhaupt and each has stated that in June 2000 Dr. Slaugenhaupt had told them that she and Dr. Gusella had discovered the major mutation. Axelrod Decl. ¶¶ 13, 28; Brownstein Decl. ¶¶ 14, 16. Like Dr. Scheidereit, both Dr. Axelrod and Dr. Brownstein are disinterested third-parties whose corroborative testimony deserves significant weight.

Dr. Anat Blumenfeld of Hadassah University Hospital ("Hadassah") in Jerusalem, Israel provided additional corroboration. From 1988 through 1993 MGH employed Dr. Blumenfeld as a post-doctoral fellow during which time she worked in Dr. Gusella's laboratory. While at Hadassah in 2000, Dr. Blumenfeld obtained blood samples from patients in Israel and the U.S. and tested those samples and provided the genetic data that those tests generated to Dr. Slaugenhaupt for use in her and Dr. Gusella's research. Tr. Blumenfeld Dep., Apr. 22, 2010 ("Blumenfeld Tr.") at 106:6-15, 110:18-23 (*see* Exhibit 11).

Before the discovery of the mutations Dr. Blumenfeld tested many patient samples for FD using the genetic marker test previously developed by the MGH scientists, performing what is known as

[4] Plaintiffs did not take the depositions of Drs. Axelrod and Brownstein although they sought and obtained permission from the Court to do so (Order, June 25, 2010 (Doc. No. 34)).

"haplotype testing." Blumenfeld Tr., 35:11-13, 105:14-106:5; Dep. Ex. 5 at BLUMENFELD000021, Dep. Ex. 16. Dr. Blumenfeld testified that in May 2000 – after Dr. Slaugenhaupt had told her that the MGH scientists had found the major mutation – she began retesting these patient samples for the major mutation using a different test specifically developed for that purpose. Blumenfeld Tr., 17:16-23, 18:11-15, 19:20-20:16, 22:11-22, 33:8-34:12, 35:18-36:2; Dep. Exs. 2, 5 at BLUMENFELD000021. Dr. Blumenfeld described how the results of the retesting were recorded in her laboratory notebook. Blumenfeld Tr., 33:8-34:12; Dep. Ex. 5 at BLUMENFELD000021. The results of that May 2000 retesting confirmed the MGH scientists' discovery of the major mutation. Blumenfeld Tr., 17:16-23. Dr. Blumenfeld, therefore, corroborates Dr. Slaugenhaupt's and Dr. Gusella's early May 2000 discovery of the major mutation. In addition, Dr. Blumenfeld testified that by August 14, 2000 she had tested hundreds or thousands of people for the major mutation discovered by the MGH scientists. Blumenfeld Tr., 47:10-18. Plaintiffs do not even claim to have discovered the major mutation by that time. Plaintiffs' Admissions, 4.

Dr. Blumenfeld corroborates Dr. Slaugenhaupt's and Dr. Gusella's early August 2000 discovery of the minor mutation as well. Dr. Blumenfeld testified about an email dated August 9, 2000 that she received from Ms. Maire Leyne, an MGH technician working with Dr. Slaugenhaupt. Blumenfeld Tr., 50:6-19; Dep. Ex. 7. That email was a response to Dr. Blumenfeld's request for additional information that she needed to order primers to do testing for "change #2" (i.e., the minor mutation). Blumenfeld Tr., 55:20-57:16; Dep. Exs. 7, 8. As Dr. Blumenfeld explained, Ms. Leyne's email explicitly identifies the G/C transition as the "Odd2" mutation (the prior name of the minor mutation). Blumenfeld Tr., 50:10-51:13; Dep. Ex. 7. Later, on August 15, 2010, Dr. Blumenfeld ordered the corresponding primers. Blumenfeld Tr., 56:1-57:16; Dep. Exs. 7, 8. She testified about the results of the testing for the minor mutation that were recorded in her laboratory notebook on August 23, 2000. Blumenfeld Tr., 61:16-64:19; Dep. Ex. 9 at BLUMENFELD000045, 49. Dr. Blumenfeld, by virtue of having received the details of the minor mutation from MGH and initiating testing for it in August 2000, corroborates Dr.

Slaugenhaupt's and Dr. Gusella's early August 2000 discovery of the minor mutation. Plaintiffs have admitted that they do not claim to have discovered the minor mutation by that time. Plaintiffs' Admissions, 4.

The Parties' Scientific Papers

Plaintiffs claim inventorship of the patents-in-suit because the American Journal of Human Genetics ("AJHG") sent a fourteen line abstract (i.e., summary) of Plaintiffs' proposed report on FD ("the Anderson Report") to Dr. Gusella on December 22, 2000 with a request that he review the report for its suitability for publication. Gusella Dep. Ex. 13. Dr. Gusella testified that the abstract and request arrived at his office while he was away for Christmas vacation and that when he returned he promptly notified the editor of the AJHG that he could not review the report. Tr. Gusella Dep., Jan. 27, 2010 ("Gusella Tr. I") at 14:12-19, 23:4-9, 30:8-17, Dep. Exs. 13, 15 (*see* Exhibit 4A). Neither he nor Dr. Slaugenhaupt received or saw the Anderson Report before its publication. Gusella Tr., 35:12-14. Tr. Slaugenhaupt Dep., Jan. 27, 2010 ("Slaugenhaupt Tr. II") at 247:9-13 (*see* Exhibit 3B). Dr. Gusella explained that he declined to review the report on ethical grounds because the abstract showed that its subject matter was related to his own research and because he and Dr. Slaugenhaupt were preparing their own paper ("the Slaugenhaupt Paper") for publication. Gusella Tr. I, 24:2-9, 30:12-17, Dep. Ex. 15. *See also* Ex. 2A. When examining the abstract at his deposition, Dr. Gusella testified that the information it contained was not sufficient to identify the mutations. Gusella Tr. I, 18:24-21:7. Ultimately, the AJHG published both the Slaugenhaupt Paper and Anderson Report in the January 2001 issue.[5]

Plaintiffs do not allege that they communicated or collaborated with Dr. Slaugenhaupt and/or Dr. Gusella regarding any FD research. Tr. Rubin Dep., Feb. 4, 2010 ("Rubin Tr.") at 147:7-9 (*see* Exhibit 12). Tr. Anderson Dep., Feb. 4, 2010 ("Anderson Tr.") at 52:20-53:6 (*see* Exhibit 13). Plaintiffs filed their provisional patent application on January 17, 2001, eleven days after Dr. Slaugenhaupt and Dr. Gusella filed their provisional application. Plaintiffs' application did not name Dr. Slaugenhaupt and Dr.

[5] A copy of the published Anderson Report is attached hereto as Exhibit 2B.

Gusella as co-inventors, which clearly indicates that Plaintiffs did not consider the MGH scientists to be collaborators or their co-inventors.[6]

The Impropriety of This Litigation

A purported telephone conversation involving Plaintiff Dr. Rubin apparently triggered Plaintiffs' dispute with MGH. Dr. Rubin testified that he had a telephone conversation with Dr. Sonia Peltzer after the public announcement of the discovery of the mutations (i.e., in January 2001). Rubin Tr., 158:1-14. Dr. Rubin claims that in that conversation Dr. Peltzer told him that Dr. Brownstein had told her that the MGH scientists had a copy of the unpublished Anderson Report "on their desk" while they were preparing the Slaugenhaupt Paper for publication. Rubin Tr., 158:15-24. Co-Plaintiff Dr. Anderson clearly shares this belief, having testified that Dr. Rubin told her of his conversation with Dr. Peltzer. Anderson Tr., 57:4-59:15. Thus, based on this multiple hearsay, Plaintiffs apparently believe that Dr. Slaugenhaupt and Dr. Gusella improperly took information from the unpublished Anderson Report, used it to identify the mutations, used it for the Slaugenhaupt Paper, and used it to acquire the patents-in-suit.

Plaintiffs suspect that persons connected with the AJHG (i.e., the editor and/or peer reviewers) provided the MGH scientists with a copy of the unpublished Anderson Report. Rubin Tr., 140:5-141:22, 156:7-157:24. But, Plaintiffs have not offered any proof in support of this allegation. None of the testimony that Plaintiffs obtained from anyone in this case, including the AJHG editor and peer reviewers of the Anderson Report, supports the allegation. Indeed, Dr. Brownstein has provided a declaration stating that he never had any discussion with Dr. Peltzer wherein he told her that the MGH scientists had a copy of the unpublished Anderson Report. Brownstein Decl. ¶¶ 22-29. Thus, Plaintiffs' dispute is based on an alleged conversation that the only competent evidence demonstrates never occurred.

The propriety of this suit further is called into question by Plaintiffs' pronouncement that Dor

[6] Plaintiffs' subsequent patent applications that claim priority to their provisional application, U.S. Serial Nos. 10/050,189 (filed Jan. 16, 2002; abandoned) and 12/339,581 (filed Dec. 19, 2008; pending), also do not name the MGH scientists as co-inventors. This reflects Plaintiffs' continuing belief that the MGH scientists are not their collaborators or co-inventors.

Yeshorim, a New York based charity that tests individuals for Jewish genetic diseases such as FD, is funding this litigation. Opp'n to MGH Mot. to Dismiss, May 27, 2010 (Doc. No. 72) at 4. *See also* Rubin Tr. 257:19-24; Tr. Ekstein Dep., Feb. 13, 2010 ("Ekstein Tr.") at 35:4-6 (*see* Exhibit 14). Rabbi Josef Ekstein is the founder and Executive Director of Dor Yeshorim. Ekstein Tr., 17:18-24. Dr. Axelrod has provided a declaration stating that she had periodic conversations with Rabbi Ekstein in 1999-2000, including one in which he expressed anger that the MGH scientists had discovered the mutations but were not immediately making a public announcement of their discovery. Axelrod Decl. ¶¶ 19-22. Dr. Axelrod also recounted a conversation with Rabbi Ekstein in a November 22, 2000 email that she sent to Dr. Blumenfeld. Axelrod Decl. ¶¶ 26-27. In that email Dr. Axelrod referred to Rabbi Ekstein's acknowledgement that Dr. Slaugenhaupt and Dr. Gusella had discovered the mutations. *Id.* Rabbi Ekstein, therefore, knew that before the AJHG editor received the Anderson Report and sent the abstract of it to Dr. Gusella that the MGH scientists had discovered the mutations. This clearly defeats Plaintiffs' already unsupported allegation that Dr. Slaugenhaupt and Dr. Gusella used an unpublished copy of the Anderson Report to identify the mutations. And, by funding this litigation, Rabbi Ekstein's organization is allowing Plaintiffs to advance claims that Rabbi Ekstein knows to be false.[7]

STATEMENT OF FACTS

The discussion above provides context to this dispute. However, pursuant to D. Mass. Local Rule 56.1, MGH provides the following statement of material facts to which MGH contends there is no genuine issue to be tried. As described below, Plaintiffs cannot prevail on these facts as a matter of law because these facts do not satisfy the threshold requirements necessary to invoke 35 U.S.C. § 256 to change the inventorship of the issued patents-in-suit.

1. To support their claim of inventorship, Plaintiffs, through their retained expert Dr. Ariella Oppenheim, rely on four pages of their laboratory records: Bates numbers RA00678 and RA00675 with

[7] Rabbi Ekstein's role in providing funding for this litigation strongly suggests that he may be the true party in interest.

regard to the major mutation and Bates numbers RA00683 and RA00674 with regard to the minor mutation (copies attached hereto as Exhibit 15). Plaintiffs' expert characterizes only two of these pages as disclosing the subject matter claimed in the patents-in-suit, namely the T/C nucleotide transition (i.e., the major mutation) (RA00675; apparently dated Sept. 19, 2000) and the G/C nucleotide transition (i.e., the minor mutation) (RA00683; apparently dated Oct. 12, 2000). The remaining pages disclose material that is not part of the claims of the patents-in-suit and, therefore, have no bearing on the inventorship of those claims.

2. Dr. Anderson testified that the RA00675 and RA00683 documents were her laboratory notes. Anderson Tr., 224:7-225:22, 235:3-15; Dep. Ex. F13 at RA00675, RA00683. She also testified that none of her laboratory notes were witnessed when she created them. Anderson, Tr. 254:15-17.

3. To support their claim of inventorship, Plaintiffs testified that they each contributed to the claims of the patents-in-suit. Rubin Tr., 138:5-10, 142:21-144:13, 144:23-145:12, 145:21-23, 146:14-23; Dep. Ex. G8 at MGH-P000001753, MGH-P000001892-93, Dep. Ex. G9 at MGH-P000001, MGH-P00000140. Anderson Tr., 31:5-32:12, 34:3-9, 36:15-37:24; Dep. Ex. F3 at MGH-P000001753, MGH-P000001892-93, MGH-P000001, MGH-P00000140. Plaintiffs testified that they each contributed to all of the claims in their own pending patent application, all of which are directed to the mutations. Rubin Tr., 135:20-136:5; Dep. Ex. G7 at RA00375-77. Anderson Tr., 22:1-4, 25:20-26:2; Dep. Ex. F2 at RA00375-377. Their testimony, therefore, reflects their belief that each is a co-inventor with respect to the other with regard to their entire alleged invention, i.e., the discovery of the major and minor mutations.

4. Plaintiffs have testified that they did not collaborate with Dr. Slaugenhaupt and Dr. Gusella. Rubin Tr., 147:7-9. Anderson Tr., 52:20-24.

5. Plaintiffs did not file their first patent application directed to the mutations (provisional patent application serial no. 60/262,284) until January 17, 2001. Exhibit 16 at 1. This is eleven days after Dr. Slaugenhaupt and Dr. Gusella filed their provisional patent application claiming the mutations.

Exhibit 17 at 1.

6. Plaintiffs have admitted that they do not assert a date of invention regarding the discovery of the major mutation before August 15, 2000 and have admitted that they do not assert a date of invention regarding the discovery of the minor mutation before September 15, 2000. Plaintiffs' Admissions, 4.

7. Dr. Blumenfeld performed testing for FD on thousands of patient samples sent to her by Rabbi Ekstein. Blumenfeld Tr., 123:22-124:24. She faxed the confidential results of that testing to Rabbi Ekstein as she generated them. Blumenfeld Tr., 124:25-125:12. She did not send these confidential results to Plaintiffs. Blumenfeld Tr., 147:12-17. Confidential results that Dr. Blumenfeld faxed to Rabbi Ekstein early in the morning on Monday, August 7, 2000 (Israel time, which was late afternoon on Sunday, August 6, 2000 U.S. time) included data obtained from her testing of samples from a group of related patients. Blumenfeld Tr., 145:4-146:2; Dep. Ex. 18 at RA04874. That data was unique because it identified the location of the mutations. Blumenfeld Tr., 150:5-20, 153:3-22; Dep. Ex. 18 at RA04874. Dr. Blumenfeld testified that having that unique data would have saved years of research into finding the mutations. Blumenfeld Tr., 150:5-20; Dep. Ex. 18 at RA04874. Plaintiffs received that confidential data from Rabbi Ekstein; indeed producing it to MGH during discovery as part of Plaintiffs' documents. Rubin Tr., 80:17-22; Dep. Ex. G4 at RA04874. Anderson Tr., 130:4-13; Dep. Ex. F5 at RA04874. By Wednesday, August 9, 2000 Plaintiffs began their analysis of blood samples from these related patients. Rubin Tr., 59:7-13; Dep. Exs. G3 at RA00070, G4 at RA04903-04. Anderson Tr., 124:9-18, 125:4-5, 126:3-5, 126:17-127:14; Dep. Exs. F5 at RA04903-04, F6 at RA00070. Plaintiffs claim to have discovered the mutations a few weeks later, having only begun their research to find the mutations a few months prior. Rubin Tr., 65:6-18. Anderson Tr., 39:2-42:4. *See also* Ex. 15 at RA00675 (major mutation), RA00683 (minor mutation).

STANDARD OF REVIEW

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any

material fact and the movant is entitled to judgment as a matter of law" by "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials; or (B) showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56. "Summary judgment is appropriate in a patent case as it is in any other case." *C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.*, 911 F.2d 670, 672 (Fed. Cir. 1990). When the summary judgment movant demonstrates the absence of a genuine dispute over any material fact, the burden shifts to the non-movant to show there is a genuine factual issue for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). The court must draw all reasonable inferences in favor of the non-movant. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007).

ARGUMENT

I. MGH is Entitled to Summary Judgment on Counts I and II Because Plaintiffs Do Not Meet the Requirements for Changing Inventorship of the Patents-in-Suit Pursuant to 35 U.S.C. § 256.

Section 256 is titled "Correction of named inventor." As its title indicates, the purpose of this section of the statute is to correct the listing of inventors on an issued patent; it is not for addressing the issue of who was first to invent, which is the province of the Patent Office's interference procedure. A party seeking to invoke this section must be a proper joint inventor of the subject matter described and claimed in the patent. Further, a party seeking to be added as an inventor of an issued patent pursuant to this section must prove his or her inventorship with evidence that satisfies the clear and convincing standard. As described below, Plaintiffs can do neither.

A. Section 256 is Inapplicable in the Absence of Joint Inventorship.

Section 256 was enacted to addresses "mistake[s] in joining a person as a joint inventor" of an issued patent. S. Rep. No. 82-1979, at 7-8 (1952), *as reprinted in* 1952 U.S.C.C.A.N. 2394, 2401 (emphasis added). Indeed, Section 256 "is limited to the correction of errors involving true joint

inventorship, and does not contemplate or permit what would amount to substitution of one inventor entirely for another under the guise of 'correction.'" *Rival Mfg. Co. v. Dazey Products Co.*, 358 F. Supp. 91, 101 (W.D. Mo. 1973). *See also Rawlplug Co., Inc. v. Hilti Aktiengesellschaft*, 777 F. Supp. 240, 243 (S.D.N.Y. 1991) (Section 256 "cannot be used to substitute one *sole* inventor for another" (citing *Dee v. Aukerman*, 625 F. Supp. 1427, 1428 (S.D. Ohio 1986)). Section 256 is, therefore, inapplicable in the absence of joint inventorship.

The statutory requirements of joint inventorship are set forth in 35 U.S.C. § 116. A person is a joint inventor only if he contributes to the conception of the claimed invention. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998); *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997); *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994). Individuals cannot be joint inventors pursuant to the statute unless there is some type of collaboration or cooperation between them. *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., Inc.*, 973 F.2d 911, 917 (Fed. Cir. 1992).

Plaintiffs do not even allege collaboration in their Complaint. Moreover, counsel for MGH asked each Plaintiff at their deposition whether he or she collaborated with Dr. Slaugenhaupt and Dr. Gusella. Without hesitation, each said no:

From Dr. Anderson's testimony:

> Q. Okay. All right. Have you ever collaborated with Dr. Slaugenhaupt?
> A. No.
> Q. Have you ever collaborated with Dr. Gusella?
> A. No.

Anderson Tr., 52:20-24.

From Dr. Rubin's testimony:

> Q. Have you ever collaborated with Dr. Gusella and Dr. Slaugenhaupt?
> A. No.

Rubin Tr., 147:7-9.

These admissions are sufficient to end the inquiry into joint inventorship. Having conceded that they did

not collaborate with Dr. Slaugenhaupt and Dr. Gusella, there is no basis for Plaintiffs to claim that they are joint inventors with them on the patents in suit. Plaintiffs, therefore, cannot invoke Section 256 because they do not meet its threshold requirement of being joint inventors. As the *Rival Mfg.* and *Rawlplug* courts explained, there can be no relief under Section 256 for individuals who are unconnected with the inventors named on an issued patent. *Rival Mfg.*, 358 F. Supp. at 101; *Rawlplug*, 777 F. Supp. at 243. Indeed, such disputes are subject matter for interference proceedings in the U.S. Patent Office.[8] MGH, therefore, submits that it is entitled to judgment in its favor on Plaintiffs' Counts I and II and respectfully urges the Court to rule accordingly.

B. Plaintiffs' Evidence of Their Purported Inventorship Does Not as a Matter of Law Meet the Clear and Convincing Burden Necessary to Disturb the Inventorship of the Patents-In-Suit.

Even if Plaintiffs were deemed somehow to satisfy the joint inventorship threshold requirement to invoke 35 U.S.C. § 256 – which they do not – their evidence of their purported inventorship does not satisfy the clear and convincing burden of proof. This deficiency is equally fatal to Plaintiffs' demands.

In support of establishing their purported inventorship, Plaintiffs rely on their own testimony and two unwitnessed pages of Plaintiff Dr. Anderson's laboratory notebook. Plaintiffs' scant uncorroborated evidence does not satisfy their clear and convincing burden of proof. There is no proof of their inventorship before the filing date of their application showing conception and a constructive reduction to practice. Therefore, summary judgment in favor of MGH is proper.

"Inventorship is a question of law with underlying factual issues." *Checkpoint Sys., Inc. All-Tag Sec. S.A.*, 412 F.3d 1331, 1338 (Fed. Cir. 2005). Issued patents are presumed valid, the inventors named on an issued patent are presumed correct, and "nonjoinder of inventors must be proven by facts supported by clear and convincing evidence." 35 U.S.C. § 282; *Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 342 F.3d 1298, 1308 (Fed. Cir. 2003), *cert. denied*, 541 U.S. 988 (2004). "The burden of showing misjoinder or nonjoinder of inventors is a heavy one … ." *Bd. of Ed. ex rel. Florida State Univ. v. Am.*

[8] For example, an interference proceeding involving Plaintiffs' pending patent application.

Bioscience, Inc., 333 F.3d 1330, 1337 (Fed. Cir. 2003). "Summary judgment is properly granted if the evidence, when viewed in a light most favorable to the non-moving party, fails to establish the inventorship of an omitted inventor by clear and convincing evidence." *Linear Technology Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1327 (Fed. Cir. 2004).

Proof of prior invention requires corroborating evidence of conception of the invention. *Stern v. Trustees of Columbia Univ.*, 434 F.3d 1375, 1378 (Fed. Cir. 2006), *cert. denied*, 549 U.S. 817 (2006). Conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986). "What is required is 'corroborating evidence of a contemporaneous disclosure that would enable one skilled in the art to make the invention.'" *Thompson v. Haynes*, 305 F.3d 1369, 1384 (Fed. Cir. 2002), citing *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994).

Whether the inventor's testimony has been sufficiently corroborated is evaluated under a "rule of reason" analysis. *Price v. Symsek*, 988 F.2d 1187, 1195 (Fed. Cir. 1993). Under this analysis, "an evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the [alleged] inventor's story may be reached." *Id.* (emphasis omitted) (citing *Coleman v. Dines*, 754 F.2d 353, 360 (Fed. Cir. 1985)). Corroborating evidence may take many forms. Reliable evidence of corroboration preferably comes in the form of physical records that were made contemporaneously with the alleged prior invention. *See Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1350-51 (Fed. Cir. 2001) ("Documentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof that the inventor's testimony has been corroborated." (citing *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1373 (Fed. Cir. 1998))). Circumstantial evidence about the inventive process may also corroborate. *See Knorr v. Pearson*, 671 F.2d 1368, 1373 (CCPA 1982) ("Sufficient circumstantial evidence of an independent nature can satisfy the corroboration rule."). Additionally, oral testimony of someone other than the alleged inventor may

corroborate. *See Price*, 988 F.2d at 1195-96.

On the other hand, a putative inventor's unwitnessed laboratory notebooks on their own are insufficient to corroborate a patent challenger's assertion of inventorship. *Stern*, 434 F.3d at 1378. Nor can an alleged prior inventor's own testimony, standing alone, provide clear and convincing evidence. *Caterpillar Inc. v. Sturman Indus., Inc.*, 387 F.3d 1358, 1377 (Fed. Cir. 2004), *cert. denied*, 545 U.S. 1114 (2005). Thus, summary judgment against a claim of inventorship has been affirmed as proper where the claimant's corroborating evidence was "terse and cryptic," "highly ambiguous," "tangential at best" and not created contemporaneously with the alleged inventive process. *Linear Technology Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1327-29 (Fed. Cir. 2004). *See also Chirichillo v. Prasser*, 30 F. Supp. 2d 1132, 1138 (E.D. Wis. 1998) (granting summary judgment against plaintiff's 35 U.S.C. § 256 claim to correct inventorship: "Corroboration usually requires some testimony by others as to the nature of the contributions or an embodiment of the invention in some clearly perceptible form, such as drawings or a model. … [The plaintiff] has not demonstrated that any potentially corroborative evidence exists. He has acknowledged that there is no documentary corroborative evidence, and has produced no affidavits other than his own.").

Plaintiffs have failed to produce any documentary, testimonial, or physical evidence corroborating their alleged invention. Although Plaintiffs have produced pages of what they claim are their laboratory records, none of them are witnessed. Indeed, the vast majority of Plaintiffs' records are those generated by Plaintiff Dr. Anderson. None of this material comes close to satisfying the corroboration requirement.

The patents-in-suit claim specific genetic mutations, i.e., a T/C transition (the major mutation) and a G/C transition (the minor mutation) at defined locations in the IKBKAP gene. The only documents that Plaintiffs produced during discovery that purportedly disclose these mutations are Dr. Anderson's notebook pages RA00675 and RA00683. For the purposes of summary judgment, however, what is important about these documents is that they are Plaintiffs' own unwitnessed words. In no instance can a putative inventor's testimony be corroborated by his or her unwitnessed laboratory records. *Procter &*

Gamble Co. v. Teva Pharmaceuticals USA, Inc., 566 F.3d 989, 998-99 (Fed. Cir. 2009). In addition, Dr. Rubin and Dr. Anderson testified that each contributed to their entire alleged invention, i.e., the discovery of the major and minor mutations, making each a co-inventor with respect to the other. The testimony of one co-inventor, however, cannot be used to help corroborate the testimony of another co-inventor. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1171 (Fed. Cir. 2006) (citing *Lacks Indus. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1350 (Fed. Cir. 2003)). Plaintiffs' attempt at cross-corroboration lacks the necessary independence and, as a matter of law, is simply inadequate to satisfy their evidentiary burden. Indeed, a putative inventor's own words can never constitute clear and convincing corroborating proof of prior invention. *Stern*, 434 F.3d at 1378; *Caterpillar*, 387 F.3d at 1377. As one district court has explained:

> Nor can the proposed inventor's own testimony be relied on, as the "temptation for even honest witnesses to reconstruct, in a manner favorable to their own position, what their state of mind may have been years earlier, is simply too great …" *Hess v. Advanced Cardiovascular Sys.*, 106 F.3d 976, 982 (Fed. Cir. 1997) …

eSpeed, Inc. v. BrokerTec USA, L.L.C., 342 F. Supp. 2d 244, 254 (D. Del. 2004), *aff'd*, 480 F. 3d 1129 (Fed. Cir. 2007).

In sum, even viewing everything in this case in the light most favorable to Plaintiffs, there is no clear and convincing evidence from which any rational trier of fact could conclude that Plaintiffs have proven that they are inventors of the patents-in-suit. There is no genuine issue for trial, and summary judgment is appropriate. *Ricci v. DeStefano*, 129 S. Ct. 2658, 2677, 557 U.S. ___ (2009) (quoting *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)).

II. MGH is Entitled to Summary Judgment on Count II in View of Plaintiffs' Admissions of No Collaboration.

In Count II of their Complaint, Plaintiffs specifically request to be added as co-inventors of the patents-in-suit. Notwithstanding Plaintiffs' failure to allege collaboration and their inability to meet the requirements for a cause of action under 35 U.S.C. § 256, Plaintiffs' own words are fatal to any claim that

they should be listed with Dr. Slaugenhaupt and Dr. Gusella as co-inventors. Simply put, Plaintiffs' testimony[9] that they did not collaborate with Dr. Slaugenhaupt and Dr. Gusella forecloses any claim of co-inventorship on Plaintiffs' part. Plaintiffs' testimony makes summary judgment in favor of MGH on this Count entirely proper, and MGH respectfully urges the Court to rule accordingly.

CONCLUSION

For the reasons set forth above, MGH submits that summary judgment in favor of MGH is appropriate and warranted, and respectfully urges the Court to rule accordingly.

Respectfully submitted,

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[9] *See infra* p. 15.

CERTIFICATE OF SERVICE PURSUANT TO LOCAL RULE 5.2(B)

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on January 10, 2011.

/s/Brian M. Gaff
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